

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN

BLAKE MANUFACTURING,)
INC.)
v. Plaintiff,) Case No. _____
TRULIFE, INC.)
Defendant.)

)

COMPLAINT

Plaintiff Blake Manufacturing, Inc. (“BMI”) alleges against defendant TruLife, Inc. (“TruLife”) as set forth below.

THE PARTIES

1. BMI is a Florida corporation with its principal place of business at 9241 Lazy Lane, Tampa, Florida 33614.
2. Upon information and belief, TruLife is a Delaware corporation with its principal place of business and registered agent located at 2010 East High Street, Jackson, Michigan 49203.

JURISDICTION AND VENUE

3. This action arises under the patent laws of the United States, 35 U.S.C. §§ 271, 281–285. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

4. TruLife is subject to personal jurisdiction in this District and subject to this Court's specific and general jurisdiction, pursuant to due process, on the grounds that it resides in this District and the state of Michigan, has committed acts of patent infringement in this District and the State of Michigan, and regularly conducts and/or solicits business, engages in other persistent courses of conduct, and/or derive substantial revenue from the sale of goods to persons or entities in this District and the State of Michigan.

5. Venue is proper in this District pursuant to 28 U.S.C. § 1400(b) because both TruLife resides in this District and/or has committed acts of infringement and has a regular and established place of business in this District.

FACTUAL BACKGROUND

6. BMI is a leading provider of orthosis devices and has invested significant resources in developing and patenting its innovative products.

7. BMI is the assignee and owner of all right, title, and interest in and to U.S. Patent No. 6,923,780, titled Foot Orthosis with Detachable Skid Sole Plate, and BMI has the sole right to any and all remedies for infringement of the '780 Patent. A true and correct copy of the '780 Patent is attached hereto as Exhibit A, and BMI's assignment is recorded at the U.S. Patent Office at reel/frame 021547/0808. The '780 Patent was duly and legally issued on August 2, 2005 and is valid and enforceable.

8. BMI is the assignee and owner of all right, title, and interest in and to U.S. Patent No. 7,163,519, titled Foot Orthosis with Detachable Skid Sole Plate, and BMI has the sole right to any and all remedies for infringement of the ‘519 Patent. A true and correct copy of the ‘519 Patent is attached hereto as Exhibit B, and BMI’s assignment is recorded at the U.S. Patent Office at reel/frame 021547/0808. The ‘519 Patent was duly and legally issued on January 16, 2007 and is valid and enforceable.

9. BMI has sold a contracture boot that is protected by the ‘780 and ‘519 Patents since at least as early as 2007 (the “BMI Boot”), and the BMI boot has been consistently marked with the ‘780 and ‘519 patent numbers in accordance with 35 U.S.C. § 287(a). A picture of the BMI Boot is attached as Exhibit C.

10. TruLife purchased the BMI Boot from BMI since at least as early as 2007, and last purchased the BMI Boot from BMI on or around January 2017.

11. TruLife is now making, selling, and/or offering for sale a boot, shown in Exhibit D (the “TruLife Boot”), which is identified as Item Number FH3002 CONTRACTURE BOOT and/or as 66906 BOOT TRU-CLEAR CONTRACTURE.

12. The TruLife Boot is nearly identical to the BMI Boot and infringes at least claims 1, 8, and 14 of the ‘780 Patent.

13. The TruLife Boot is nearly identical to the BMI Boot and infringes at least claims 1 and 6 of the ‘519 Patent.

14. On July 29, 2019, BMI sent a letter to TruLife expressly identifying the existence of the ‘780 and ‘519 Patents, the TruLife Boot, and example claims of the ‘780 and ‘519 Patents that are infringed by the TruLife Boot. A copy of the July 29, 2019 letter is attached as Exhibit E.

15. BMI’s July 29, 2019 letter was delivered to TruLife on July 30, 2019, as shown in the receipt attached as Exhibit F.

16. TruLife did not substantively respond to BMI’s July 29, 2019 letter.

COUNT I

(Direct Infringement of U.S. Patent No. 6,923,780)

17. BMI incorporates by reference all previous allegations as though set forth fully here.

18. TruLife has infringed and continues to infringe one or more claims of the ‘780 Patent under 35 U.S.C. § 271(a), literally and/or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing into the United States the TruLife Boot.

19. TruLife’s infringing acts are without license or authorization from BMI.

20. Due to TruLife's long history of purchasing the BMI Boot, which is marked with the numbers of the '780 and '519 Patents, TruLife knew or should have known that its actions constitute infringement of the '780 and '519 Patents. And yet TruLife has continued in its infringement. TruLife's infringement is therefore willful and continuing, and this case is exceptional under 35 U.S.C. § 285.

21. By no later than TruLife's July 30, 2019 receipt of the July 29, 2019 letter described above, TruLife knew or should have known that its actions constitute infringement of the '780 and '519 Patents. And yet TruLife has continued in its infringement and ignored BMI's letter. TruLife's infringement is therefore willful and continuing, and this case is exceptional under 35 U.S.C. § 285.

22. As a direct and proximate result of BMI's infringement of the '780 Patent, BMI has suffered and will continue to suffer injury for which it is entitled to damages under 35 U.S.C. § 284 adequate to compensate it for such infringement, in an amount to be proven at trial, as well as enhanced damages. BMI's damages include its lost profits, but are in no event less than a reasonable royalty.

23. As a direct and proximate result of TruLife's infringement of the '780 Patent, BMI has also suffered irreparable injury for which it has no adequate

remedy at law. Unless TruLife is permanently enjoined from further infringement of the ‘780 Patent, BMI will continue to suffer irreparable injury and impairment of the value of its patent rights.

COUNT II

(Direct Infringement of U.S. Patent No. 7,163,519)

24. BMI incorporates by reference all previous allegations as though set forth fully here.

25. TruLife has infringed and continues to infringe one or more claims of the ‘519 Patent under 35 U.S.C. § 271(a), literally and/or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing into the United States the TruLife Boot.

26. TruLife’s infringing acts are without license or authorization from BMI.

27. Due to TruLife’s long history of purchasing the BMI Boot, which is marked with the numbers of the ‘780 and ‘519 Patents, TruLife knew or should have known that its actions constitute infringement of the ‘780 and ‘519 Patents. And yet TruLife has continued in its infringement. TruLife’s infringement is therefore willful and continuing, and this case is exceptional under 35 U.S.C. § 285.

28. By no later than TruLife's July 30, 2019 receipt of the July 29, 2019 letter described above, TruLife knew or should have known that its actions constitute infringement of the '780 and '519 Patents. And yet TruLife has continued in its infringement and ignored BMI's letter. TruLife's infringement is therefore willful and continuing, and this case is exceptional under 35 U.S.C. § 285.

29. As a direct and proximate result of BMI's infringement of the '519 Patent, BMI has suffered and will continue to suffer injury for which it is entitled to damages under 35 U.S.C. § 284 adequate to compensate it for such infringement, in an amount to be proven at trial, as well as enhanced damages. BMI's damages include its lost profits, but are in no event less than a reasonable royalty.

30. As a direct and proximate result of TruLife's infringement of the '519 Patent, BMI has also suffered irreparable injury for which it has no adequate remedy at law. Unless TruLife is permanently enjoined from further infringement of the '519 Patent, BMI will continue to suffer irreparable injury and impairment of the value of its patent rights.

PRAYER FOR RELIEF

In light of the foregoing, plaintiff BMI respectfully prays for the following relief against defendant TruLife:

- A. A judgment that TruLife has infringed one or more of the claims of the ‘780 Patent (either literally or under the doctrine of equivalents);
- B. A permanent injunction enjoining TruLife, its officers, directors, employees, agents, representatives, parent companies, subsidiaries, and affiliates, and all persons acting in active concert or participation therewith, from engaging in any continued infringement of the ‘780 Patent;
- C. An award of all damages to which BMI is entitled under 35 U.S.C. § 284 for all past and continuing infringement of the ‘780 Patent, including but not limited to all lost profits and/or reasonable royalties, and an order requiring a full accounting of the same;
- D. An award of enhanced damages in accordance with the provisions of 35 U.S.C. § 284 as a result of TruLife’s knowing and willful infringement of the ‘780 Patent;
- E. A judgment that TruLife has infringed one or more of the claims of the ‘519 Patent (either literally or under the doctrine of equivalents);
- F. A permanent injunction enjoining TruLife, its officers, directors, employees, agents, representatives, parent companies, subsidiaries, and affiliates, and all persons acting in active concert or participation therewith, from engaging in any continued infringement of the ‘519 Patent;

G. An award of all damages to which BMI is entitled under 35 U.S.C. § 284 for all past and continuing infringement of the ‘519 Patent, including but not limited to all lost profits and/or reasonable royalties, and an order requiring a full accounting of the same;

H. An award of enhanced damages in accordance with the provisions of 35 U.S.C. § 284 as a result of TruLife’s knowing and willful infringement of the ‘519 Patent;

I. A finding that this case is exceptional under 35 U.S.C. § 285 and an award of all of the attorneys’ fees incurred by BMI in this action;

J. An assessment of interest, both pre- and post-judgment, on the damages awarded;

K. An award of costs incurred by BMI in bringing and prosecuting this action; and

L. Any other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38(b), BMI hereby demands a jury trial on all issues so triable.

Dated: December 12, 2019

Respectfully submitted

By: /s/ Larry J. Saylor
Larry J. Saylor (P28165)
MILLER, CANFIELD, PADDOCK
& STONE P.L.C.
150 West Jefferson Avenue, Suite 2500
Detroit, Michigan 48226
Telephone: (313) 496-7986
saylor@millercanfield.com

A. Justin Poplin*
LATHROP GAGE LLP
10851 Mastin Blvd.
Building 82, Suite 1000
Overland Park, KS 66210
Tel: 913.451.5100
Fax: 913.451.0875
jpoplin@lathropgage.com

Travis W. McCallon*
LATHROP GAGE LLP
2345 Grand Boulevard, Suite 2200
Kansas City, MO 64108
Tel: 816.292.2000
Fax: 816.292.2001
tmccallon@lathropgage.com
(*Admission pending)

EXHIBIT A



US006923780B2

(12) **United States Patent**
Price et al.

(10) Patent No.: **US 6,923,780 B2**
(45) Date of Patent: **Aug. 2, 2005**

(54) **FOOT ORTHOSIS WITH DETACHABLE SKID SOLE PLATE**(76) Inventors: **Mary Price**, 13804 Sumac Pl., Tampa, FL (US) 33625; **Steve Price**, 13804 Sumac Pl., Tampa, FL (US) 33625

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 55 days.

(21) Appl. No.: **10/434,640**(22) Filed: **May 9, 2003**(65) **Prior Publication Data**

US 2004/0082895 A1 Apr. 29, 2004

(51) Int. Cl.⁷ **A61F 5/00**(52) U.S. Cl. **602/27; 602/5**

(58) Field of Search 36/59, 62, 66; 602/5, 27, 28, 29, 65, 6; 2/24, 62, 22

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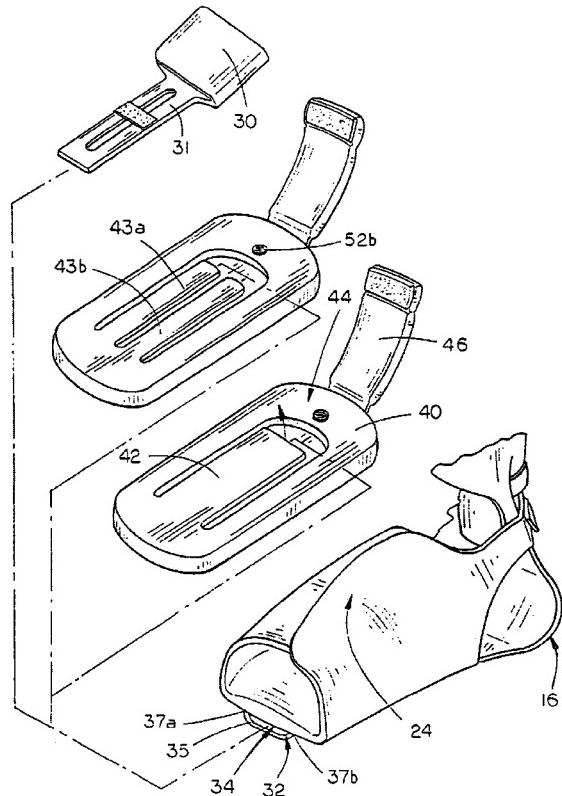
Primary Examiner—Henry Bennett

Assistant Examiner—Dinnatia Doster-Greene

(74) Attorney, Agent, or Firm—Adam H. Jacobs

(57) **ABSTRACT**

A foot orthosis includes a generally "L"-shaped splint having a generally upright leg-engaging section and a forwardly-extending foot support section with at least a portion of the splint being substantially transparent. A generally flexible foot receiving and retaining boot is removably mounted on the splint for releasably securing a foot on the splint, and a tongue-receiving pocket is mounted on one of the splint and the boot, the tongue-receiving pocket having at least one opening and a tongue retaining section therein. A generally planar skid pad includes an attached tongue section projecting from the skid pad, and the tongue section of the skid pad is insertable into the tongue-receiving pocket such that the tongue is releasably secured in the tongue-receiving pocket and the skid pad is thus releasably secured on one of the splint and the boot.

16 Claims, 4 Drawing Sheets

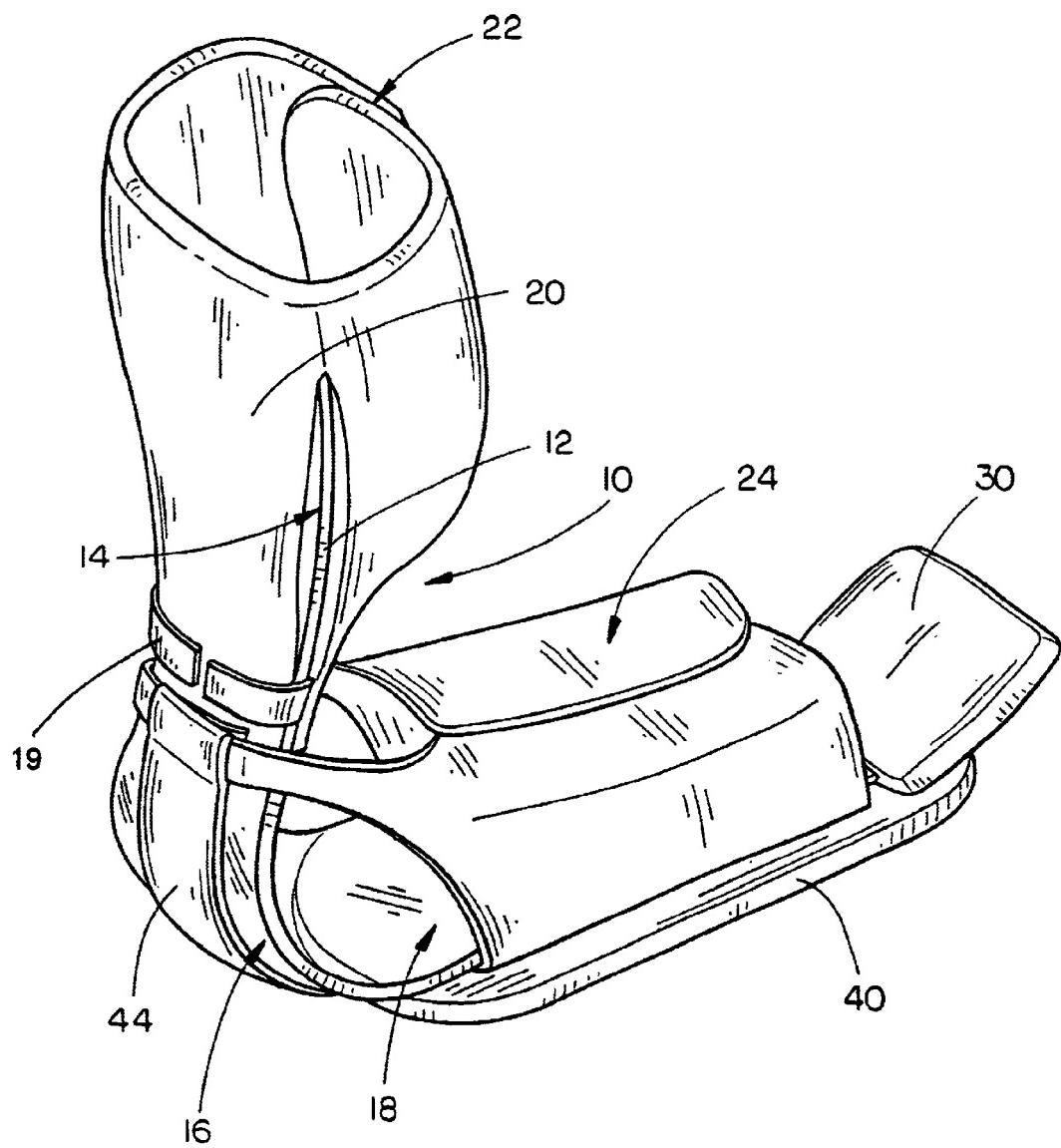


FIG. 1

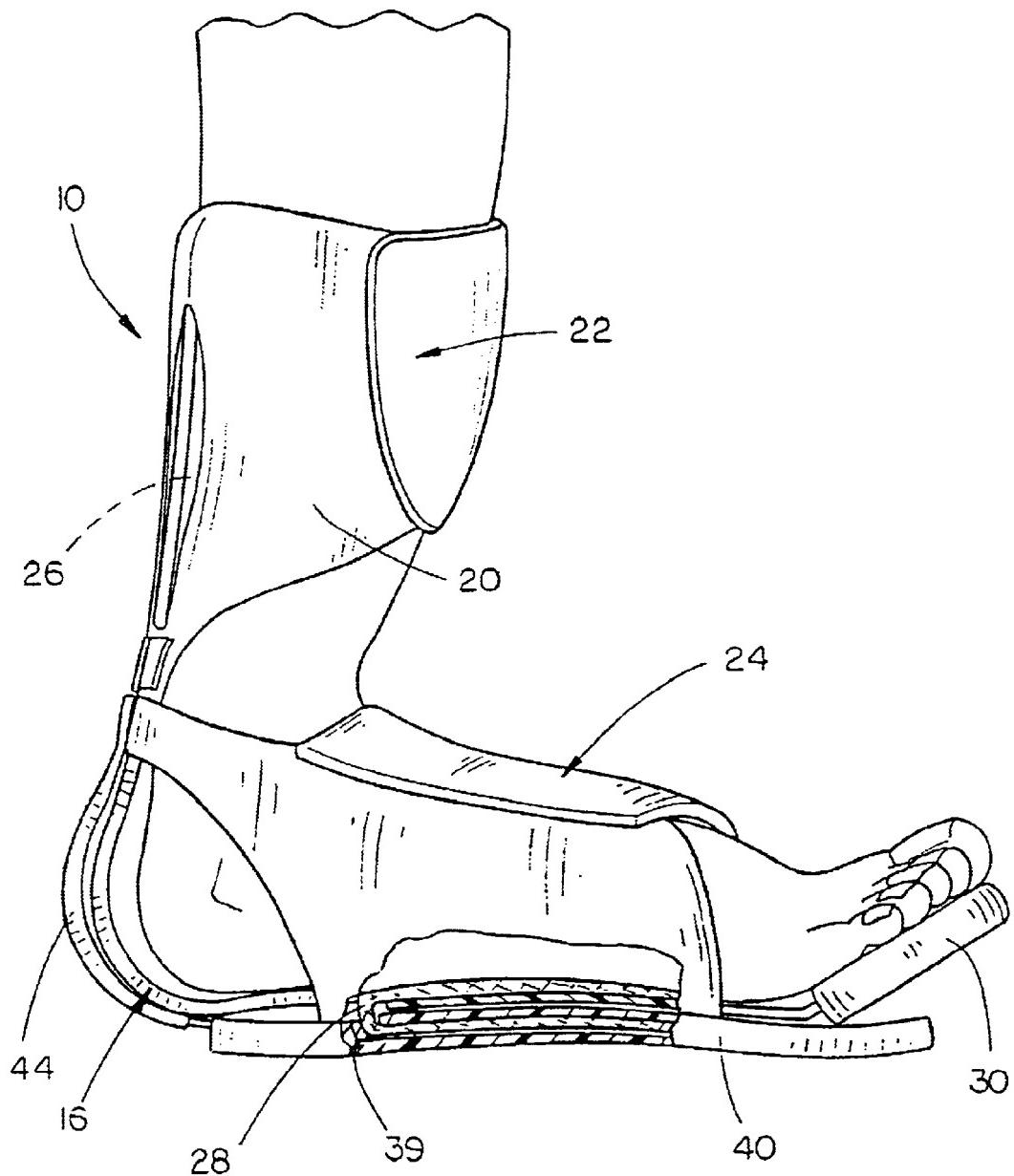


FIG. 2

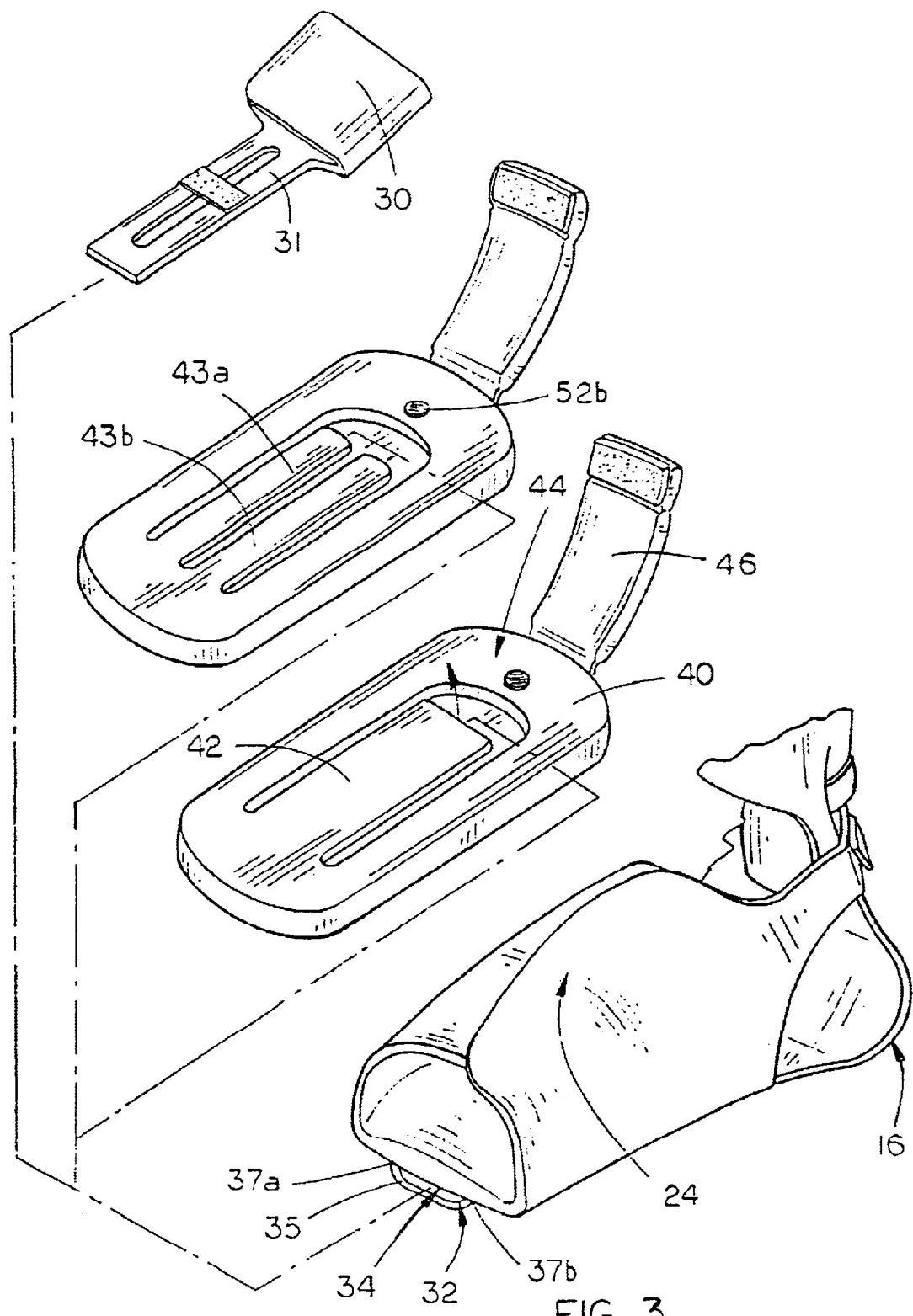


FIG. 3

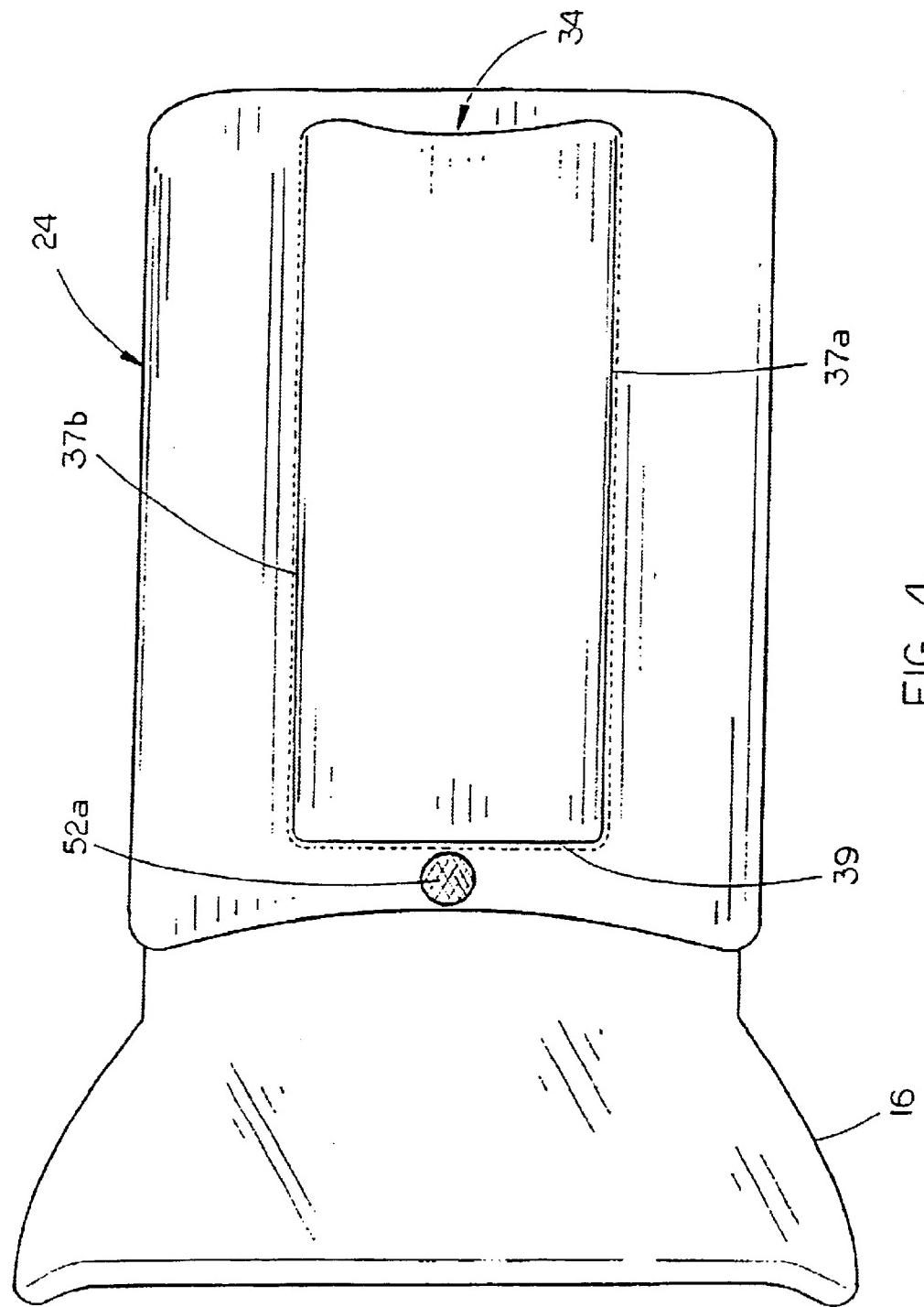


FIG. 4

1**FOOT ORTHOSIS WITH DETACHABLE SKID SOLE PLATE****BACKGROUND OF THE INVENTION****1. Technical Field**

The present invention relates to orthotic devices for feet and, more particularly, to a foot orthosis having a generally L-shaped lower leg and foot support splint having a transparent heel section permitting viewing of the heel and a skid pad having a tongue for insertion into a tongue-receiving pocket on the underside of the boot for releasably securing the skid pad on the boot.

2. Description of the Prior Art

Numerous types of devices intended to immobilize the lower leg and foot of a human patient are available. Examples of simple devices such as casts or splints are well known in the art. Other more recent devices provide certain limited immobilization and protection benefits but, because of their design, do not provide protection against immobilization problems such as decubitus ulcers (pressure sores).

Accordingly, there is a need for a multi-function orthosis for the foot, heel, ankle and lower leg which provides three-dimensional immobilization and protection benefits, minimizes the risk of pressure sores on the heel and posterior portion of the lower leg, provides a range of therapeutic pressures and positions for the foot, yet still allows ambulation of the patient without removal of the device. An important feature of such devices found in the prior art is the inclusion of a frictional skid pad or sole plate which is attached to the underside of the orthotic device and helps to prevent slipping. Each of the devices in the prior art that include such a skid pad attaches the skid pad to the orthotic device by hardware such as a bolt and nut arrangement or the like which extends from the orthotic device for the skid pad to be mounted thereto. A major disadvantage of this design, however, is that the hardware is directly underneath the patient's foot and this often impedes walking on the injured extremity, which can jeopardize the rehabilitation of the injury. Furthermore, the risk of walking is increased by many of the devices of the prior art due to the invasive hardware on the underside of the devices, which increases the chance for injury and thus increases the potential liability of the care giver, which unfortunately has become a prime consideration in the operation of such facilities. There is therefore a need for a foot and ankle orthotic device which substantially eliminates the underfoot hardware of the prior art.

Another problem encountered in the prior art is that when the orthotic devices include a toe plate, which is a support plate mounted forwardly on the orthotic device beneath the toes, the adjustment mechanism for the toe plate is often the same type of invasive hardware as that found in connection with the skid pad mounting hardware. When the toe plate is connected by a nut and bolt arrangement as is found on the vast majority of prior art devices, the nurse or care provider must unscrew the nut to adjust the toe plate, which can cause further aggravation to the injured extremity, particularly if the nut has been tightened previously and tools are needed to perform the adjustment. There is therefore a need for a toe plate mounting and adjustment arrangement which will substantially eliminate the underfoot hardware of the prior art.

Thus, an object of the present invention is to provide an improved foot orthosis.

Another object of the present invention is to provide an improved foot orthosis which substantially eliminates the

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dangers inherent in the prior art caused by the nut and bolt combination used for securement of the skid pad to the orthotic device.

Another object of the present invention is to provide an improved foot orthosis which substantially eliminates the dangers inherent in the prior art caused by the hardware mounting of the toe plate on the orthotic device.

Another object of the present invention is to provide an improved foot orthosis which includes a skid pad having a projecting tongue section which fits within and is releasably secured by a tongue-receiving pocket mounted on the underside of the foot orthosis.

Another object of the present invention is to provide an improved foot orthosis which includes a toe plate having a tongue portion which is inserted into and releasably secured within the pocket thereby eliminating the invasive hardware of the prior art.

Finally, an object of the present invention is to provide an improved foot orthosis which is relatively simple and durable in construction and is safe and effective in use.

SUMMARY OF THE INVENTION

The present invention provides a foot orthosis which includes a generally "L"-shaped splint having a generally upright leg-engaging section and a forwardly-extending foot support section with at least a portion of the splint being substantially transparent. A flexible foot receiving and retaining boot is removably mounted on the splint for releasably securing a foot on the splint, and a tongue-receiving pocket is mounted on one of the splint and the boot, the tongue-receiving pocket having at least one opening and a tongue retaining section therein. A generally planar skid pad includes an attached tongue section projecting from the skid pad, and the tongue section of the skid pad is insertable into the tongue-receiving pocket such that the tongue is releasably secured in the tongue-receiving pocket and the skid pad is releasably secured on one of the splint and the boot.

The combination of the tongue and pocket substantially eliminates the need for invasive or potentially injurious hardware to be mounted on the underside of the foot orthosis of the present invention. Furthermore, as the skid pad can be removed or replaced by merely sliding the tongue out of and into the pocket, movement of the foot orthosis and hence the injured extremity is greatly reduced, thus preventing further injury to the extremity. Finally, the pocket and/or tongue may be modified to include a fastening material such as hook and loop fasteners or the like to ensure that the skid pad remains in place on the foot orthosis while not adding potentially damaging hardware to the device. It is thus seen that the present invention provides a substantial improvement over those devices found in the prior art.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the present invention;

FIG. 2 is a side elevational view of the foot orthosis of the present invention;

FIG. 3 is a detailed exploded perspective view showing the attachment of the skid pad and toe plate to the boot; and

FIG. 4 is a bottom plan view showing the pocket.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The foot orthosis 10 of the present invention includes an L-shaped semi-flexible splint 12 having an extended leg-

engaging section 14, a relatively wide heel portion 16, a forwardly extending foot support section 18 and an anti-rotation bar 19 to prevent lower extremity rotation, as shown best in FIGS. 1-3. Preferably, the L-shaped splint 12 would be constructed of a transparent PVC plastic such as Clear-dex™ or KYDEX™ having a small degree of flexibility to permit minor motion of the leg and foot. It has been found that the plastic thickness should be between $\frac{1}{8}$ " and $\frac{1}{2}$ ", although the thickness is not critical to the present invention. The benefits of the transparent material being used will be detailed later in this disclosure.

A fabric boot 20 is fitted on and removably mounted to the L-shaped splint 12 and would preferably include leg and foot access flaps 22 and 24 to permit the foot orthosis 10 to be fitted onto the leg and foot of the wearer of the foot orthosis 10, as shown in FIG. 2. In the preferred embodiment, the boot 20 would be constructed of a washable polyester tricot fabric or the like, although the exact material used is not critical so long as the securement characteristics of the boot 20 are maintained. It is further preferred that the leg access flap 22 and the foot access flap 24 be releasably securable by hook and loop securement devices or the like to receive and comfortably retain the leg and foot of the wearer there within, and further that the unit include padding to protect sensitive injured parts of the patient from further damage.

As shown best in FIGS. 1 and 2, the heel portion of fabric boot 20 is open to permit viewing of the heel within the foot orthosis 10 and thereby facilitate diagnosis of the foot condition of the patient. The transparent nature of the L-shaped splint 12 further facilitates the viewing of the heel of the patient through the foot orthosis 10 without mandating removal of the foot orthosis 10 to conduct such inspection. It thus becomes far easier for doctors, nurses and other staff to inspect the heel of the patient wearing the foot orthosis 10 and thus confirm that degradation of the heel is not taking place due to extended periods of bed rest or the like. The design of the L-shaped splint 12 is such that the patient's heel is "floated" to virtually eliminate heel contact with a resting surface, which is a common cause of bed sores for bed ridden patients.

Additional features found in the present invention would include an Achilles support pad 26 mounted on the boot 20 adjacent the leg support portion 14 of the L-shaped splint 12 which provides additional padding for the Achilles tendon of the patient, which is particularly important when the patient is recumbent for extended periods of time. Additionally, a foot pad 28 is provided on the fabric boot 20 adjacent foot support section 18 to permit the heel of the patient to "float" during walking, which is particularly important for those patients with decubitus or other such bone and tendon degradation maladies caused by long periods of bed rest.

It is to be understood that many of the above described elements of the present invention are generally found in the prior art, are generally conventional and do not in and of themselves comprise the inventive elements of the present invention. However, one of the problems found in foot orthotic devices of the prior art which is not addressed is that to attach or remove elements to the foot section 18 of the L-shaped splint 12 requires the use of a nut and bolt arrangement, such as that shown in Varn, U.S. Pat. No. 5,569,173. This means that the majority of prior art devices include a screw mounted on the underside of the foot section of the splint, which is generally regarded as invasive hardware and can potentially result in injury to the patient due to the location of the screw on the orthotic device. Furthermore, as the toe plate 30 is commonly secured to the

L-shaped splint 12 by the same nut and bolt combination, removal of and adjustment of the toe plate 30 mandates adjustment of the nut and bolt combination, further risking injury to the patient wearing the orthotic device due to the twisting and turning of the nut and bolt.

The present invention substantially eliminates the dangers inherent in the prior art caused by the nut and bolt combination by inventing and including the following functional features. The skid pad 40 is preferably a rounded generally rectangular pad of closed cell expanded vinyl, the skid pad 40 including a tongue portion 42 mounted on the upper surface 44 of the skid pad 40, as shown best in FIGS. 2 and 3. It is preferred that the construction material used in connection with the skid pad 40 be extremely durable such that the skid pad 40 and tongue 42 have an extended usable lifespan, which is superior to those devices found in the prior art. The skid pad 40 may also include a layer of textured rubber to keep the skid from slipping, although it may be of any type of appropriate non-skid material. Preferably, the tongue 42 consists of a cut out section of skid pad 40 which is separated from skid pad 40 along the longitudinal length thereof and remains attached at the forward end thereof to permit the tongue 42 to be pivoted upwards from the skid pad 40. Mounted on the underside of fabric boot 20 is a tongue-receiving pocket 32, which is generally rectangular in shape and extends longitudinally along the underside of fabric boot 20 and includes a forward opening 34. The pocket 32 includes an outer wall 35 which is generally semi-cylindrical in shape and has left and right longitudinal edges 37a and 37b which are each connected to the underside of the fabric boot 20 thus leaving a tongue-receiving cavity having a forward opening 34 for receiving the tongue 42 therein. The rear edge 39 of the outer wall 35 is likewise connected to the underside of fabric boot 20 thus creating the tongue-receiving pocket 32 as shown in FIGS. 3 and 4. In the preferred embodiment, tongue 42 of skid pad 40 would be slid into forward opening 34 of tongue-receiving pocket 32 until tongue 42 is securely seated within the tongue-retaining section of tongue-receiving pocket 32, as shown best in FIG. 2. Because pocket 32 is only slightly larger than tongue 42, there is substantial frictional contact between tongue 42 and the interior of the tongue-receiving pocket 32 which prevents the tongue 42 from sliding out of tongue-receiving pocket 32 absent intentional force being applied to remove tongue 42 from tongue-receiving pocket 32. No other bottom-mounted securement means is necessary to secure tongue 42 within tongue-receiving pocket 32 and thus it is seen that the intrusive hardware found in the prior art is eliminated by the present invention. However, to insure that the skid pad 40 stays on the foot orthosis 10, a strap 46 is connected to the skid pad 40 and extends rearwardly therefrom for connection to the boot 20 at a position behind and above the skid pad 40. The strap 46 would preferably include a section of hook and loop securement fabric mounted on the rearward end thereof for attachment to the boot 20, the attachment shown best in FIGS. 1 and 2.

Although it is preferred that the tongue 42 and tongue-receiving pocket 32 utilize only frictional securement to secure the tongue therein, it has been found that for those patients that are more ambulatory than average, it is sometimes desirable to enhance the frictional securement of the tongue 42 within the tongue-receiving pocket 32 by including a supplemental fastening device such as a fabric-type fastening device mounted on the underside of the fabric boot 20 immediately rearward of the tongue-receiving pocket 32, as shown best in FIGS. 3 and 4. This fastening device would consist of two separatable mating sections, one section 52a

mounted on the fabric boot 20 and the other section 52b mounted on the upper surface of the skid pad 40. While various types of fastening devices may be used with the present invention, such as hook and loop fasteners and the like, in the preferred embodiment, a fastener manufactured by 3M of Minnesota has been found to provide excellent securement while being generally non-invasive. The fastener is marketed under the name "3M Dual Lock Reclosable Fastener" and consists of hundreds of mushroom-shaped stems which interlock with one another, producing an audible "snap" which announces that the fastener is locked. Of course, various other types of fasteners can be used with the present invention, although it has been found that this type of fastening device provides secure and safe fastening of the skid pad 40 to the fabric boot 20.

Additionally, the toe plate 30 is secured on the L-shaped splint 12 by a rearward extending tongue portion 31 which fits within and is releasably secured in tongue-receiving pocket 32 by a small strip of hook and loop fastening fabric or the like which may be mounted on the tongue portion 31 or in the pocket 32. In this manner, the toe plate 30 may be positioned forwards or rearwards relative to the foot support section 18 of L-shaped splint 12 by merely sliding the toe plate in and out of the tongue-receiving pocket 32. When the toe plate 30 is in its desired position, the small strip of hook and loop fastener will be secured to the interior wall of tongue-receiving pocket 32 and the toe plate 30 would thus be releasably secured in the desired position.

It is thus seen that the skid pad 40 and toe plate 30 may be quickly and easily removed from the foot orthosis 10 of the present invention without requiring the patient to lift or move his or her foot or requiring the staff person to unscrew a nut to access the skid pad 40 or toe plate 30. Many of the potential problems involved in staff-patient contact are thus eliminated, rendering the present invention far superior to those devices found in the prior art. The ease of removal and attachment of the skid pad 40 and toe plate 30 are especially important with patients who are ambulatory and thus require the addition or removal of those elements several times during the day.

One modification that should be noted is that it may be beneficial to include more than one tongue-receiving pocket which will interact with multiple skid pad tongues 43a and 43b, as shown in FIG. 3, in order to provide additional frictional securement for the skid pad 40 on the boot 20. To that end, it should be noted that the precise number, size and shape of the pockets is not critical to the invention so long as the functional characteristics of the invention are maintained, specifically that the pocket receive and releasably retain the tongue.

It is to be understood that numerous modifications, additions and substitutions may be made to the foot orthosis of the present invention which fall within the intended broad disclosure. For example, the construction materials used in the present invention may be modified and/or changed so long as the functional characteristics of the present invention are maintained. Also, the precise size, shape and nature of the tongue 42 and tongue-receiving pocket 32 may be modified so long as the functional characteristics of the pocket are maintained, specifically the ease of removability and retention of skid pad 40. Finally, the size and shape of the invention may be modified so long as the functional characteristics are not destroyed or greatly modified.

There has thus been shown and described a foot orthotic device which accomplishes at least all of the intended objectives.

We claim:

1. A foot orthosis comprising;
a generally "L"-shaped splint having a generally upright leg-engaging section and a forwardly-extending foot support section;

a generally flexible foot receiving and retaining boot mounted on said splint for releasably securing a foot on said splint;

a tongue-receiving pocket mounted on one of said splint and said boot, said tongue-receiving pocket having at least one opening and a tongue retaining section;

a generally planar skid pad including an attached tongue section projecting from said skid pad; and

said tongue section of said skid pad being insertable into said tongue-receiving pocket such that said tongue is releasably secured in said tongue-receiving pocket and said skid pad is releasably secured on one of said splint and said boot.

2. The foot orthosis of claim 1 further comprising a forwardly extending toe plate which includes a forward toe support plate and a rearwardly extending tongue portion which fits within and is releasably secured in said tongue-receiving pocket such that said toe plate may be positioned forwards or rearwards relative to said foot support section of said L-shaped splint by sliding said tongue portion of said toe plate into and out of said tongue-receiving pocket.

3. The foot orthosis of claim 1 wherein said generally "L"-shaped splint is constructed of a semi-flexible, generally transparent PVC plastic such that the healing status of the foot is viewable without requiring removal of said splint.

4. The foot orthosis of claim 1 wherein said boot further comprises a leg access flap and a foot access flap each operative to allow a respective leg and foot to be inserted into said boot, said boot being constructed of a fabric material and said leg access flap and said foot access flap each further comprising securement means for releasably securing a leg and foot within said boot by at least one hook and loop securement device.

5. The foot orthosis of claim 1 wherein said tongue-receiving pocket comprises a longitudinally extended generally semi-cylindrical curved outer wall having left and right longitudinal edges and a rear edge, said outer wall mounted on the underside of said boot with said left and right longitudinal edges and said rear edge connected to said boot, said curved outer wall and said boot thereby forming said tongue-receiving pocket having one opening for receiving and releasably retaining said tongue therein.

6. The foot orthosis of claim 1 wherein said tongue of said skid pad comprises a cut out section of said skid pad which is separated from said skid pad along the longitudinal length thereof and remains attached at the forward end thereof thereby permitting said tongue to be pivoted upwards from said skid pad for insertion into said tongue-receiving pocket.

7. The foot orthosis of claim 1 further comprising at least two tongue-receiving pockets.

8. A foot orthosis comprising;
a generally "L"-shaped splint having a generally upright leg-engaging section and a forwardly-extending foot support section;

a generally flexible foot receiving and retaining boot mounted on said splint for releasably securing a foot on said splint;

a tongue-receiving pocket mounted on one of said splint and said boot, said tongue-receiving pocket having at least one opening and a tongue retaining section;

a generally planar skid pad including an attached tongue section projecting from said skid pad;

a forwardly extending toe plate which includes a forward toe support plate and a rearwardly extending tongue portion; and

said tongue section of said skid pad and said tongue portion of said toe plate each being insertable into said tongue-receiving pocket such that said tongue section of said skid pad and said tongue portion of said toe plate are each releasably secured in said tongue-receiving pocket and said skid pad and said toe plate are releasably secured on one of said splint and said boot.

9. The foot orthosis of claim **8** wherein said generally "L"-shaped splint is constructed of a semi-flexible, generally transparent PVC plastic such that the healing status of the foot is viewable without requiring removal of said splint.

10. The foot orthosis of claim **8** wherein said boot further comprises a leg access flap and a foot access flap each operative to allow a respective leg and foot to be inserted into said boot, said boot being constructed of a fabric material and said leg access flap and said foot access flap each further comprising securing means for releasably securing a leg and foot within said boot by at least one hook and loop securing device.

11. The foot orthosis of claim **8** wherein said tongue-receiving pocket comprises a longitudinally extended generally semi-cylindrical curved outer wall having left and right longitudinal edges and a rear edge, said outer wall mounted on the underside of said boot with said left and right longitudinal edges and said rear edge connected to said boot, said curved outer wall and said boot thereby forming said tongue-receiving pocket having one opening for receiving and releasably retaining said tongue therein.

12. The foot orthosis of claim **8** wherein said tongue of said skid pad comprises a cut out section of said skid pad which is separated from said skid pad along the longitudinal length thereof and remains attached at the forward end thereof thereby permitting said tongue to be pivoted upwards from said skid pad for insertion into said tongue-receiving pocket.

13. The foot orthosis of claim **8** further comprising at least two tongue-receiving pockets.

14. A foot orthosis comprising:
a splint for supporting a human foot;
a foot receiving and retaining boot mounted on said splint
for releasably securing a foot on said splint;
a tongue-receiving pocket mounted on one of said splint
and said boot, said tongue-receiving pocket having at
least one opening and a tongue retaining section;
a skid pad including a projecting tongue section; and
said tongue section of said skid pad being insertable into
said tongue-receiving pocket such that said tongue is
releasably secured in said tongue-receiving pocket and
said skid pad is releasably secured on one of said splint
and said boot.

15. The foot orthosis of claim **14** wherein said tongue section of said skid pad is frictionally secured within said tongue-receiving pocket.

16. The foot orthosis of claim **15** wherein said tongue section of said skid pad is additionally releasably secured within said tongue-receiving pocket by a supplemental fastening means.

* * * * *

EXHIBIT B



US007163519B2

(12) **United States Patent**
Price et al.

(10) **Patent No.:** US 7,163,519 B2
(45) **Date of Patent:** *Jan. 16, 2007

(54) **FOOT ORTHOSIS WITH DETACHABLE AND ADJUSTABLE TOE PLATE**(76) Inventors: **Mary Price**, 13804 Sumac Pl., Tampa, FL (US) 33625; **Steve Price**, 13804 Sumac Pl., Tampa, FL (US) 33625

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: 10/956,872

(22) Filed: Oct. 1, 2004

(65) **Prior Publication Data**

US 2005/0043662 A1 Feb. 24, 2005

Related U.S. Application Data

(63) Continuation of application No. 10/434,640, filed on May 9, 2003, now Pat. No. 6,923,780.

(51) **Int. Cl.**A61F 5/00 (2006.01)
A61F 5/37 (2006.01)(52) **U.S. Cl.** 602/27; 602/23; 602/5;
128/882(58) **Field of Classification Search** 36/59,
36/62, 66; 602/27, 28, 29, 65; 2/24, 62,
2/22

See application file for complete search history.

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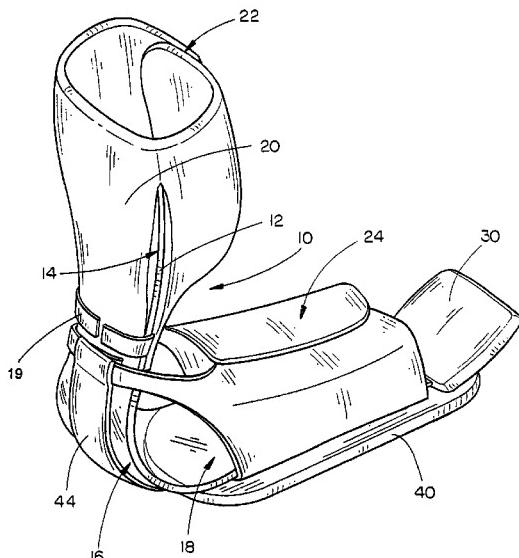
Primary Examiner—Henry Bennett

Assistant Examiner—Kari Petrik

(74) Attorney, Agent, or Firm—Adam H. Jacobs

(57) **ABSTRACT**

A foot orthosis includes a generally "L"-shaped splint having a generally upright leg-engaging section and a forwardly-extending foot support section with at least a portion of the splint being substantially transparent. A generally flexible foot receiving and retaining boot is removably mounted on the splint for releasably securing a foot on the splint, and a tongue-receiving pocket is mounted on one of the splint and the boot, the tongue-receiving pocket having at least one opening and a tongue retaining section therein. A generally planar skid pad includes an attached tongue section projecting from the skid pad, and the tongue section of the skid pad is insertable into the tongue-receiving pocket such that the tongue is releasably secured in the tongue-receiving pocket and the skid pad is thus releasably secured on one of the splint and the boot.

8 Claims, 4 Drawing Sheets

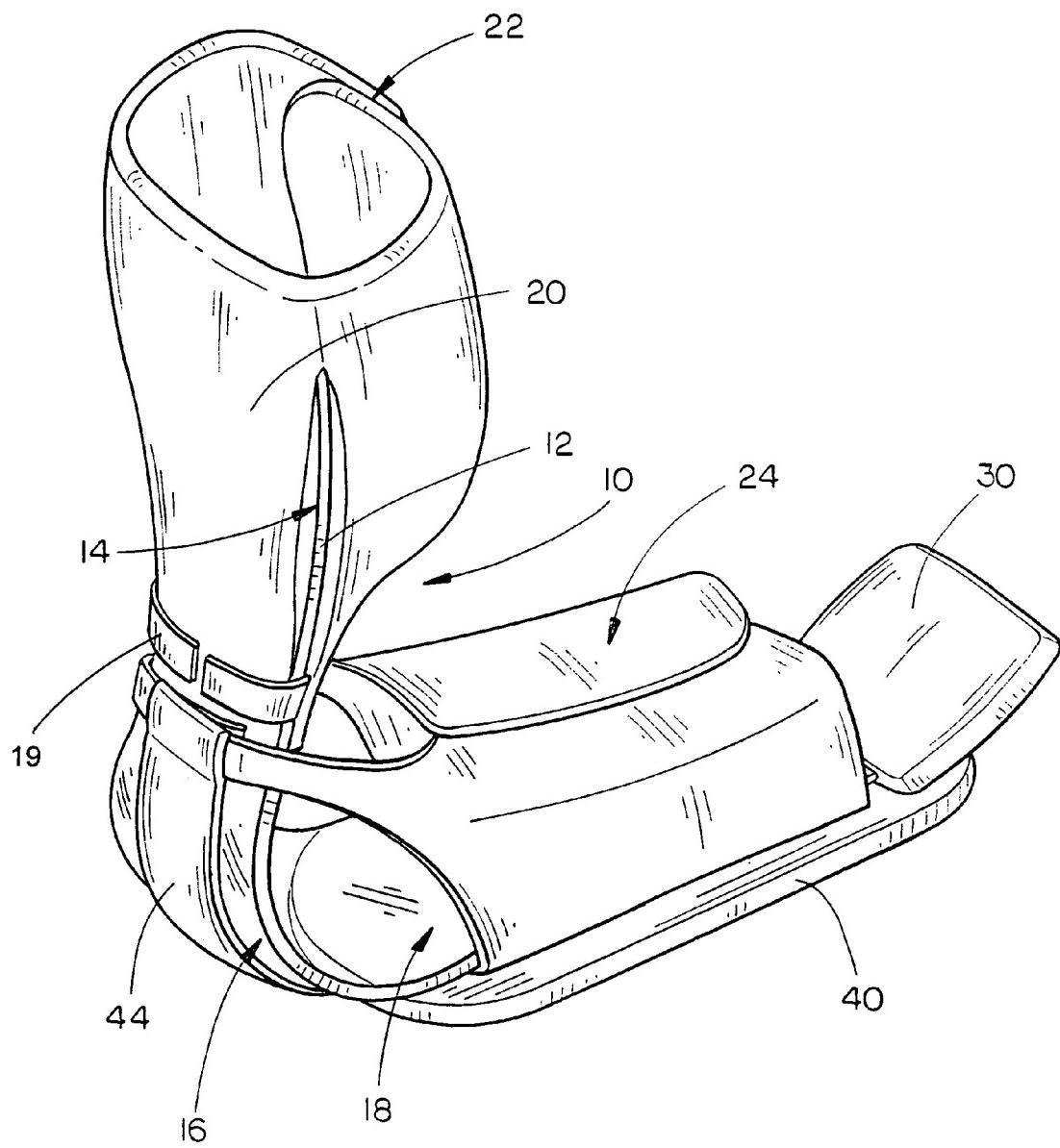


FIG. 1

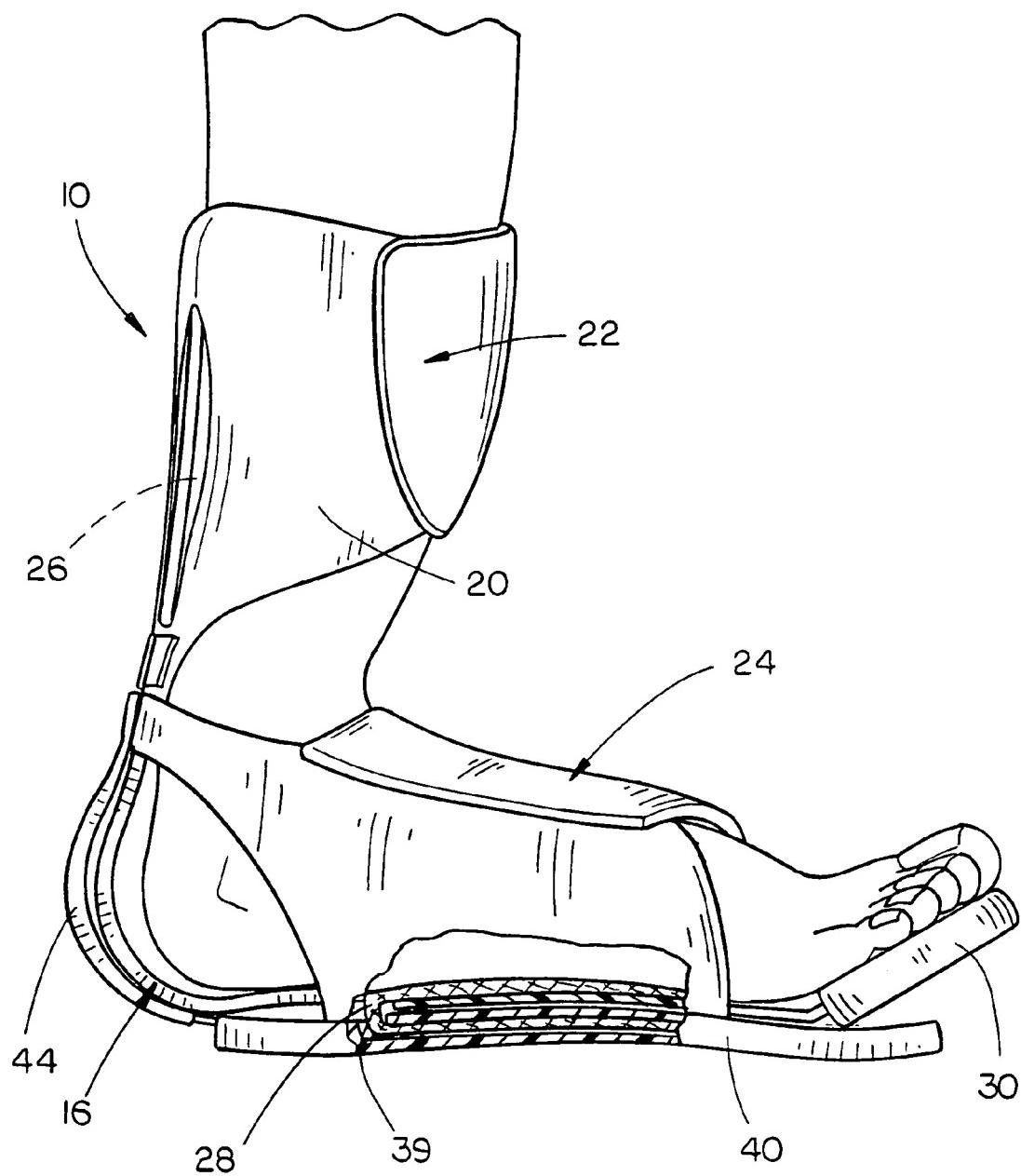


FIG. 2

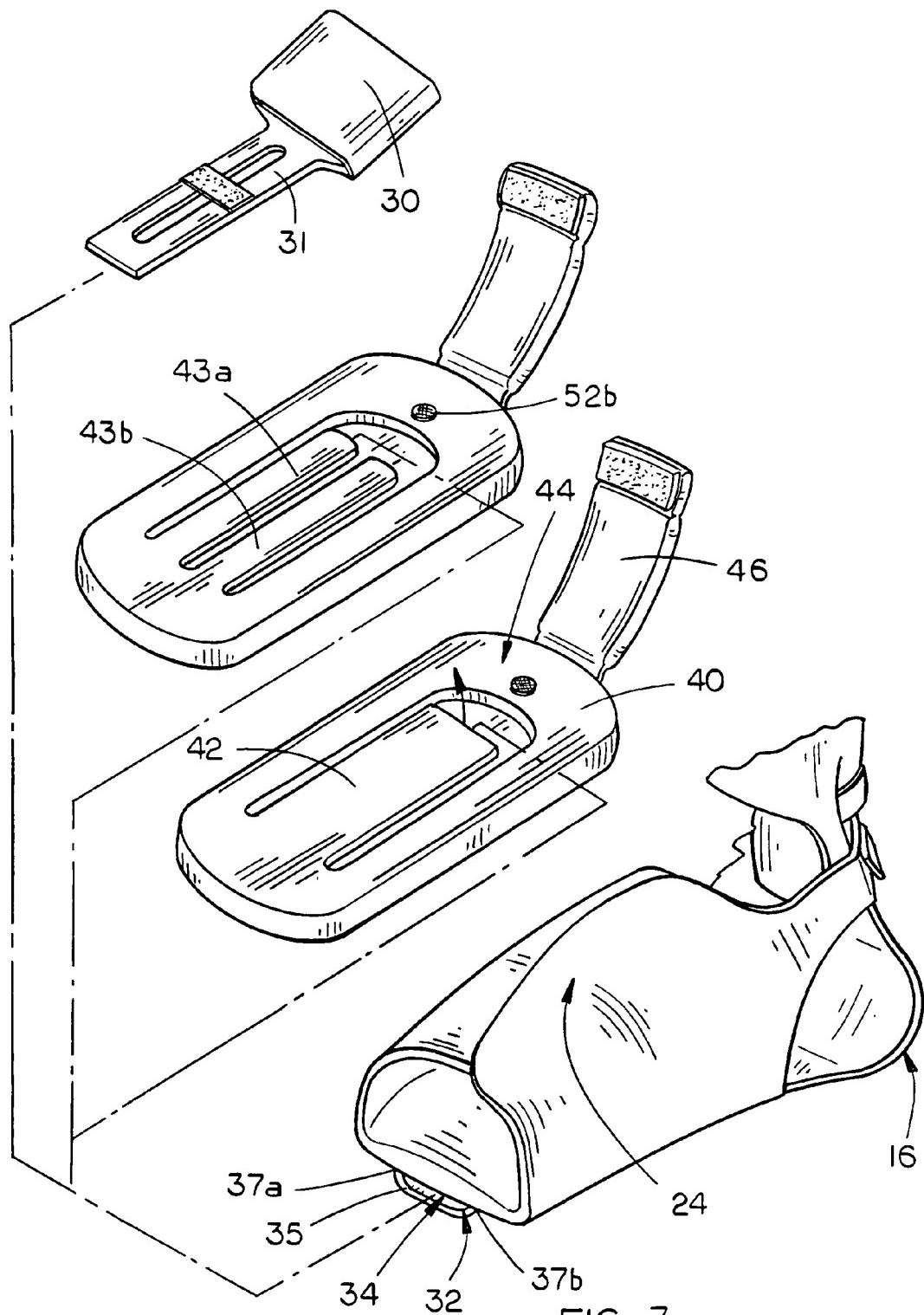


FIG. 3

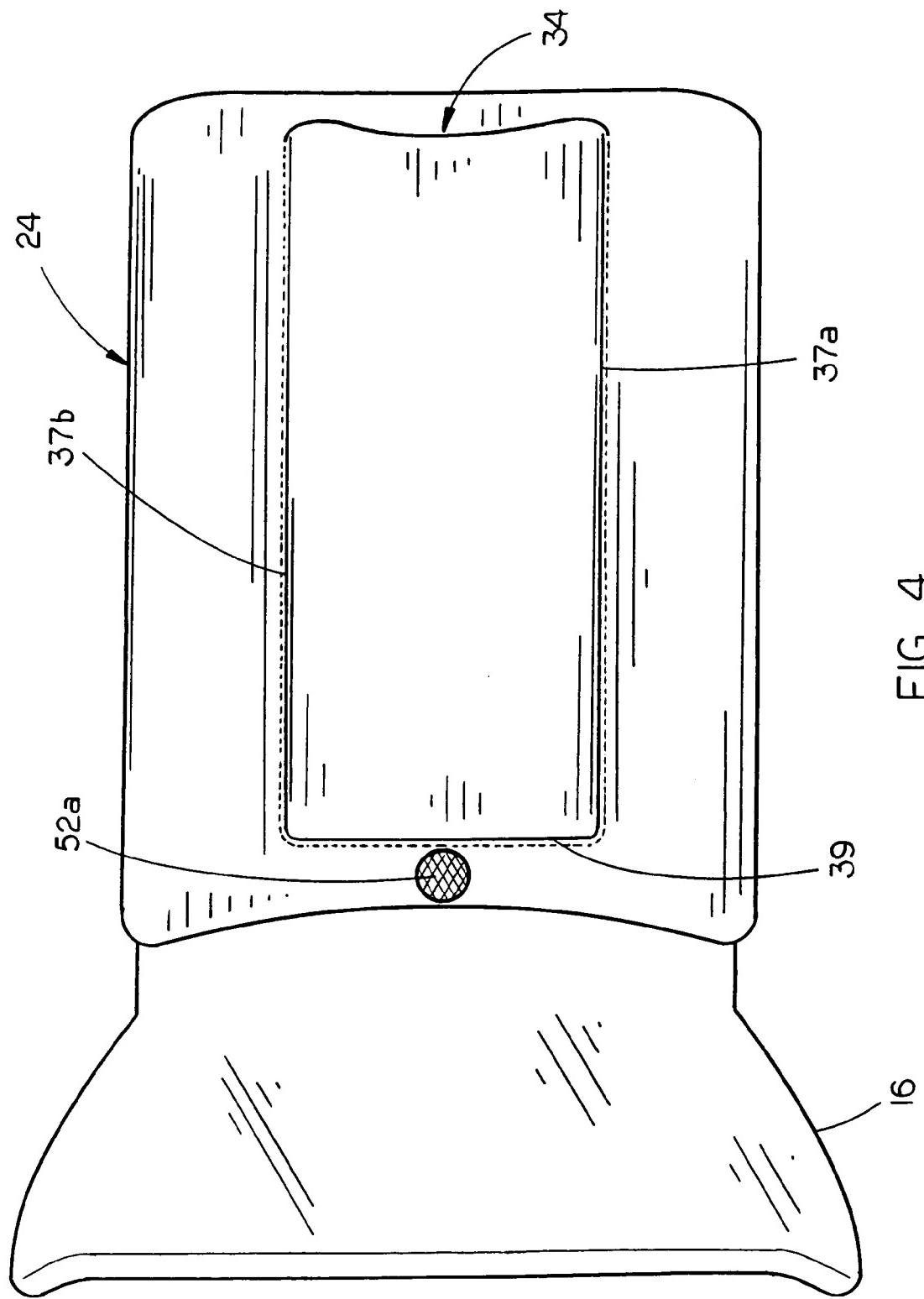


FIG. 4

1

**FOOT ORTHOSIS WITH DETACHABLE AND
ADJUSTABLE TOE PLATE**

**CROSS-REFERENCE TO RELATED
APPLICATION**

This continuation application claims priority to the filing date of related utility patent application ser. No. 10/434,640 filed May 9, 2003.

BACKGROUND OF THE INVENTION

1. Technical Field

The present invention relates to orthotic devices for feet and, more particularly, to a foot orthosis having a generally L-shaped lower leg and foot support splint having a transparent heel section permitting viewing of the heel and a skid pad having a tongue for insertion into a tongue-receiving pocket on the underside of the boot for releasably securing the skid pad on the boot.

2. Description of the Prior Art

Numerous types of devices intended to immobilize the lower leg and foot of a human patient are available. Examples of simple devices such as casts or splints are well known in the art. Other more recent devices provide certain limited immobilization and protection benefits but, because of their design, do not provide protection against immobilization problems such as decubitus ulcers (pressure sores).

Accordingly, there is a need for a multi-function orthosis for the foot, heel, ankle and lower leg which provides three-dimensional immobilization and protection benefits, minimizes the risk of pressure sores on the heel and posterior portion of the lower leg, provides a range of therapeutic pressures and positions for the foot, yet still allows ambulation of the patient without removal of the device. An important feature of such devices found in the prior art is the inclusion of a frictional skid pad or sole plate which is attached to the underside of the orthotic device and helps to prevent slipping. Each of the devices in the prior art that include such a skid pad attaches the skid pad to the orthotic device by hardware such as a bolt and nut arrangement or the like which extends from the orthotic device for the skid pad to be mounted thereto. A major disadvantage of this design, however, is that the hardware is directly underneath the patient's foot and this often impedes walking on the injured extremity, which can jeopardize the rehabilitation of the injury. Furthermore, the risk of walking is increased by many of the devices of the prior art due to the invasive hardware on the underside of the devices, which increases the chance for injury and thus increases the potential liability of the care giver, which unfortunately has become a prime consideration in the operation of such facilities. There is therefore a need for a foot and ankle orthotic device which substantially eliminates the underfoot hardware of the prior art.

Another problem encountered in the prior art is that when the orthotic devices include a toe plate, which is a support plate mounted forwardly on the orthotic device beneath the toes, the adjustment mechanism for the toe plate is often the same type of invasive hardware as that found in connection with the skid pad mounting hardware. When the toe plate is connected by a nut and bolt arrangement as is found on the vast majority of prior art devices, the nurse or care provider must unscrew the nut to adjust the toe plate, which can cause further aggravation to the injured extremity, particularly if the nut has been tightened previously and tools are needed to perform the adjustment. There is therefore a need for a toe

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plate mounting and adjustment arrangement which will substantially eliminate the underfoot hardware of the prior art.

Thus, an object of the present invention is to provide an improved foot orthosis.

Another object of the present invention is to provide an improved foot orthosis which substantially eliminates the dangers inherent in the prior art caused by the nut and bolt combination used for securing of the skid pad to the orthotic device.

Another object of the present invention is to provide an improved foot orthosis which substantially eliminates the dangers inherent in the prior art caused by the hardware mounting of the toe plate on the orthotic device.

Another object of the present invention is to provide an improved foot orthosis which includes a skid pad having a projecting tongue section which fits within and is releasably secured by a tongue-receiving pocket mounted on the underside of the foot orthosis.

Another object of the present invention is to provide an improved foot orthosis which includes a toe plate having a tongue portion which is inserted into and releasably secured within the pocket thereby eliminating the invasive hardware of the prior art.

Finally, an object of the present invention is to provide an improved foot orthosis which is relatively simple and durable in construction and is safe and effective in use.

SUMMARY OF THE INVENTION

The present invention provides a foot orthosis which includes a generally "L"-shaped splint having a generally upright leg-engaging section and a forwardly-extending foot support section with at least a portion of the splint being substantially transparent. A flexible foot receiving and retaining boot is removably mounted on the splint for releasably securing a foot on the splint, and a tongue-receiving pocket is mounted on one of the splint and the boot, the tongue-receiving pocket having at least one opening and a tongue retaining section therein. A generally planar skid pad includes an attached tongue section projecting from the skid pad, and the tongue section of the skid pad is insertable into the tongue-receiving pocket such that the tongue is releasably secured in the tongue-receiving pocket and the skid pad is releasably secured on one of the splint and the boot.

The combination of the tongue and pocket substantially eliminates the need for invasive or potentially injurious hardware to be mounted on the underside of the foot orthosis of the present invention. Furthermore, as the skid pad can be removed or replaced by merely sliding the tongue out of and into the pocket, movement of the foot orthosis and hence the injured extremity is greatly reduced, thus preventing further injury to the extremity. Finally, the pocket and/or tongue may be modified to include a fastening material such as hook and loop fasteners or the like to ensure that the skid pad remains in place on the foot orthosis while not adding potentially damaging hardware to the device. It is thus seen that the present invention provides a substantial improvement over those devices found in the prior art.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the present invention;
FIG. 2 is a side elevational view of the foot orthosis of the present invention;

FIG. 3 is a detailed exploded perspective view showing the attachment of the skid pad and toe plate to the boot; and FIG. 4 is a bottom plan view showing the pocket.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The foot orthosis 10 of the present invention includes an L-shaped semi-flexible splint 12 having an extended leg-engaging section 14, a relatively wide heel portion 16, a forwardly extending foot support section 18 and an anti-rotation bar 19 to prevent lower extremity rotation, as shown best in FIGS. 1-3. Preferably, the L-shaped splint 12 would be constructed of a transparent PVC plastic such as Clear-dex™ or KYDEX™ having a small degree of flexibility to permit minor motion of the leg and foot. It has been found that the plastic thickness should be between $\frac{1}{8}$ " and $\frac{1}{2}$ ", although the thickness is not critical to the present invention. The benefits of the transparent material being used will be detailed later in this disclosure.

A fabric boot 20 is fitted on and removably mounted to the L-shaped splint 12 and would preferably include leg and foot access flaps 22 and 24 to permit the foot orthosis 10 to be fitted onto the leg and foot of the wearer of the foot orthosis 10, as shown in FIG. 2. In the preferred embodiment, the boot 20 would be constructed of a washable polyester tricot fabric or the like, although the exact material used is not critical so long as the securement characteristics of the boot 20 are maintained. It is further preferred that the leg access flap 22 and the foot access flap 24 be releasably securable by hook and loop securement devices or the like to receive and comfortably retain the leg and foot of the wearer there within, and further that the unit include padding to protect sensitive injured parts of the patient from further damage.

As shown best in FIGS. 1 and 2, the heel portion of fabric boot 20 is open to permit viewing of the heel within the foot orthosis 10 and thereby facilitate diagnosis of the foot condition of the patient. The transparent nature of the L-shaped splint 12 further facilitates the viewing of the heel of the patient through the foot orthosis 10 without mandating removal of the foot orthosis 10 to conduct such inspection. It thus becomes far easier for doctors, nurses and other staff to inspect the heel of the patient wearing the foot orthosis 10 and thus confirm that degradation of the heel is not taking place due to extended periods of bed rest or the like. The design of the L-shaped splint 12 is such that the patient's heel is "floated" to virtually eliminate heel contact with a resting surface, which is a common cause of bed sores for bed ridden patients.

Additional features found in the present invention would include an Achilles support pad 26 mounted on the boot 20 adjacent the leg support portion 14 of the L-shaped splint 12 which provides additional padding for the Achilles tendon of the patient, which is particularly important when the patient is recumbent for extended periods of time. Additionally, a foot pad 28 is provided on the fabric boot 20 adjacent foot support section 18 to permit the heel of the patient to "float" during walking, which is particularly important for those patients with decubitus or other such bone and tendon degradation maladies caused by long periods of bed rest.

It is to be understood that many of the above described elements of the present invention are generally found in the prior art, are generally conventional and do not in and of themselves comprise the inventive elements of the present invention. However, one of the problems found in foot orthotic devices of the prior art which is not addressed is that

to attach or remove elements to the foot section 18 of the L-shaped splint 12 requires the use of a nut and bolt arrangement, such as that shown in Varn, U.S. Pat. No. 5,569,173. This means that the majority of prior art devices 5 include a screw mounted on the underside of the foot section of the splint, which is generally regarded as invasive hardware and can potentially result in injury to the patient due to the location of the screw on the orthotic device. Furthermore, as the toe plate 30 is commonly secured to the L-shaped splint 12 by the same nut and bolt combination, removal of and adjustment of the toe plate 30 mandates 10 adjustment of the nut and bolt combination, further risking injury to the patient wearing the orthotic device due to the twisting and turning of the nut and bolt.

15 The present invention substantially eliminates the dangers inherent in the prior art caused by the nut and bolt combination by inventing and including the following functional features. The skid pad 40 is preferably a rounded generally rectangular pad of closed cell expanded vinyl, the skid pad

20 including a tongue portion 42 mounted on the upper surface 44 of the skid pad 40, as shown best in FIGS. 2 and 3. It is preferred that the construction material used in connection with the skid pad 40 be extremely durable such that the skid pad 40 and tongue 42 have an extended usable 25 lifespan, which is superior to those devices found in the prior art. The skid pad 40 may also include a layer of textured rubber to keep the skid from slipping, although it may be of any type of appropriate non-skid material. Preferably, the tongue 42 consists of a cut out section of skid pad 40 which 30 is separated from skid pad 40 along the longitudinal length thereof and remains attached at the forward end thereof to permit the tongue 42 to be pivoted upwards from the skid pad 40. Mounted on the underside of fabric boot 20 is a tongue-receiving pocket 32, which is generally rectangular 35 in shape and extends longitudinally along the underside of fabric boot 20 and includes a forward opening 34. The pocket 32 includes an outer wall 35 which is generally semi-cylindrical in shape and has left and right longitudinal edges 37a and 37b which are each connected to the under-

40 side of the fabric boot 20 thus leaving a tongue-receiving cavity having a forward opening 34 for receiving the tongue 42 therein. The rear edge 39 of the outer wall 35 is likewise connected to the underside of fabric boot 20 thus creating the tongue-receiving pocket 32 as shown in FIGS. 3 and 4. In 45 the preferred embodiment, tongue 42 of skid pad 40 would be slid into forward opening 34 of tongue-receiving pocket 32 until tongue 42 is securely seated within the tongue-retaining section of tongue-receiving pocket 32, as shown best in FIG. 2. Because pocket 32 is only slightly larger than tongue 42, there is substantial frictional contact between

50 tongue 42 and the interior of the tongue-receiving pocket 32 which prevents the tongue 42 from sliding out of tongue-receiving pocket 32 absent intentional force being applied to remove tongue 42 from tongue-receiving pocket 32. No 55 other bottom-mounted securement means is necessary to secure tongue 42 within tongue-receiving pocket 32 and thus it is seen that the intrusive hardware found in the prior art is eliminated by the present invention. However, to insure that the skid pad 40 stays on the foot orthosis 10, a strap 46 is

60 connected to the skid pad 40 and extends rearwardly therefrom for connection to the boot 20 at a position behind and above the skid pad 40. The strap 46 would preferably include a section of hook and loop securement fabric mounted on the rearward end thereof for attachment to the boot 20, the 65 attachment shown best in FIGS. 1 and 2.

Although it is preferred that the tongue 42 and tongue-receiving pocket 32 utilize only frictional securement to

secure the tongue therein, it has been found that for those patients that are more ambulatory than average, it is sometimes desirable to enhance the frictional securement of the tongue 42 within the tongue-receiving pocket 32 by including a supplemental fastening device such as a fabric-type fastening device mounted on the underside of the fabric boot 20 immediately rearward of the tongue-receiving pocket 32, as shown best in FIGS. 3 and 4. This fastening device would consist of two separable mating sections, one section 52a mounted on the fabric boot 20 and the other section 52b mounted on the upper surface of the skid pad 40. While various types of fastening devices may be used with the present invention, such as hook and loop fasteners and the like, in the preferred embodiment, a fastener manufactured by 3M of Minnesota has been found to provide excellent securement while being generally non-invasive. The fastener is marketed under the name "3M Dual Lock Reclosable Fastener" and consists of hundreds of mushroom-shaped stems which interlock with one another, producing an audible "snap" which announces that the fastener is locked. Of course, various other types of fasteners can be used with the present invention, although it has been found that this type of fastening device provides secure and safe fastening of the skid pad 40 to the fabric boot 20.

Additionally, the toe plate 30 is secured on the L-shaped splint 12 by a rearward extending tongue portion 31 which fits within and is releasably secured in tongue-receiving pocket 32 by a small strip of hook and loop fastening fabric or the like which may be mounted on the tongue portion 31 or in the pocket 32. In this manner, the toe plate 30 may be positioned forwards or rearwards relative to the foot support section 18 of L-shaped splint 12 by merely sliding the toe plate in and out of the tongue-receiving pocket 32. When the toe plate 30 is in its desired position, the small strip of hook and loop fastener will be secured to the interior wall of tongue-receiving pocket 32 and the toe plate 30 would thus be releasably secured in the desired position.

It is thus seen that the skid pad 40 and toe plate 30 may be quickly and easily removed from the foot orthosis 10 of the present invention without requiring the patient to lift or move his or her foot or requiring the staff person to unscrew a nut to access the skid pad 40 or toe plate 30. Many of the potential problems involved in staff-patient contact are thus eliminated, rendering the present invention far superior to those devices found in the prior art. The ease of removal and attachment of the skid pad 40 and toe plate 30 are especially important with patients who are ambulatory and thus require the addition or removal of those elements several times during the day.

One modification that should be noted is that it may be beneficial to include more than one tongue-receiving pocket which will interact with multiple skid pad tongues 43a and 43b, as shown in FIG. 3, in order to provide additional frictional securement for the skid pad 40 on the boot 20. To that end, it should be noted that the precise number, size and shape of the pockets is not critical to the invention so long as the functional characteristics of the invention are maintained, specifically that the pocket receive and releasably retain the tongue.

It is to be understood that numerous modifications, additions and substitutions may be made to the foot orthosis of the present invention which fall within the intended broad disclosure. For example, the construction materials used in the present invention may be modified and/or changed so long as the functional characteristics of the present invention are maintained. Also, the precise size, shape and nature of the tongue 42 and tongue-receiving pocket 32 may be

modified so long as the functional characteristics of the pocket are maintained, specifically the ease of removability and retention of skid pad 40. Finally, the size and shape of the invention may be modified so long as the functional characteristics are not destroyed or greatly modified.

There has thus been shown and described a foot orthotic device which accomplishes at least all of the intended objectives.

We claim:

1. A foot orthosis comprising;
a generally "L"-shaped splint having a generally upright leg-engaging section and a forwardly-extending foot support section;
a generally flexible foot receiving and retaining boot mounted on said splint for releasably securing a foot on said splint;
a tongue-receiving pocket mounted on one of said splint and said boot, said tongue-receiving pocket having at least one opening and a tongue retaining section;
a forwardly extending toe plate which includes a forward toe support plate and a rearwardly extending tongue portion; and
said rearwardly extending tongue portion adapted to fit within and be releasably secured in said tongue-receiving pocket such that said toe plate may be positioned forwards or rearwards relative to said foot support section of said L-shaped splint by sliding said tongue portion of said toe plate into and out of said tongue-receiving pocket whereby said toe plate is releasably secured on one of said splint and said boot.

2. The foot orthosis of claim 1 wherein said generally "L"-shaped splint is constructed of a semi-flexible, generally transparent PVC plastic such that the healing status of the foot is viewable without requiring removal of said splint.

3. The foot orthosis of claim 1 wherein said boot further comprises a leg access flap and a foot access flap each operative to allow a respective leg and foot to be inserted into said boot, said boot being constructed of a fabric material and said leg access flap and said foot access flap each further comprising securement means for releasably securing a leg and foot within said boot by at least one hook and loop securement device.

4. The foot orthosis of claim 1 wherein said tongue-receiving pocket comprises a longitudinally extended generally semi-cylindrical curved outer wall having left and right longitudinal edges and a rear edge, said outer wall mounted on the underside of said boot with said left and right longitudinal edges and said rear edge connected to said boot, said curved outer wall and said boot thereby forming said tongue-receiving pocket having one opening for receiving and releasably retaining said tongue portion of said toe plate therein.

5. The foot orthosis of claim 1 further comprising at least two tongue-receiving pockets.

6. A foot orthosis comprising;
a splint for supporting a human foot;
a foot receiving and retaining boot mounted on said splint for releasably securing a foot on said splint;
a tongue-receiving pocket mounted on one of said splint and said boot, said tongue-receiving pocket having at least one opening and a tongue retaining section;
a toe plate which includes a forward toe support plate and a rearwardly extending tongue portion; and
said tongue portion of said toe plate being insertable and releasably securable in said tongue-receiving pocket such that said toe plate may be positioned forwards or

rearwards relative to said splint by sliding said tongue portion of said toe plate into and out of said tongue-receiving pocket.

7. The foot orthosis of claim 6 wherein said tongue portion of said toe plate is frictionally secured within said tongue-receiving pocket. 5

8. The foot orthosis of claim 6 wherein said tongue portion of said toe plate is additionally releasably secured within said tongue-receiving pocket by a supplemental fastening means.

* * * * *

EXHIBIT C



EXHIBIT D



EXHIBIT E



A. JUSTIN POPLIN
DIRECT: 913.451.5130

MAIN: 913.451.5100
FAX: 913.451.0875
JPOPLIN@LATHROPGAGE.COM
LATHROPGAGE.COM

BUILDING 82, SUITE 1000
10851 MASTIN BOULEVARD
OVERLAND PARK, KANSAS 66210-1669

July 29, 2019

VIA PRIORITY EXPRESS MAIL

Noel Murphy, President
TruLife, Inc.
2010 East High Street
Jackson, Michigan 49203

Shawn Boss, Registered Agent
TruLife, Inc.
2010 East High Street
Jackson, Michigan 49203

Re: Infringement of U.S. Patent Nos. 6,923,780 and 7,163,519

Dear Mr. Murphy and Mr. Boss:

We represent Blake Manufacturing, Inc. ("BMI") in intellectual property matters. BMI owns all rights to U.S. Pat. No. 6,923,780 and U.S. Pat. No. 7,163,519, and its rights are recorded with the U.S. Patent Office at reel/frame 021547/0808. Copies of both patents are enclosed.

As TruLife, Inc. is aware, BMI is a leader in orthosis devices—since at least as early as 2007, TruLife purchased BMI's contracture boot that is protected by the '780 and '519 Patents. TruLife knows of BMI's patents, as both patent numbers were prominently featured on the numerous boots that BMI has sold to TruLife for resale.

BMI recently learned that, after TruLife USA stopped purchasing contracture boots from BMI, it began selling nearly identical contracture boots made by TruLife or another party. Indeed, the boots are so similar that it appears TruLife used information it

was aware of and had access to (e.g., drawings and material specifications) regarding BMI's CE marking.

I have reviewed a sample of those boots purchased from AliMed as Item Number FH30002 CONTRACTURE BOOT "Distributed by: TruLife,"¹ and it is covered by at least claims 1, 8, and 14 of U.S. Pat. No. 6,923,780 and at least claims 1 and 6 of U.S. Pat. No. 7,163,519.

BMI expended significant resources developing its patented boot, and TruLife's willful infringement is flagrant. 35 U.S.C. § 271(a) provides that, "Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." In addition, 35 U.S.C. §§ 283-285 provide a patent holder with remedies that include injunction, damages, and attorney fees for the violation of a patent. In cases of willful infringement, damages can be trebled. *See, e.g., Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923 (2016).

BMI demands that you:

- (1) immediately cease manufacturing, importing, selling, and offering to sell contracture boots that infringe the '780 Patent and/or the '519 Patent—including but not limited to the contracture boot discussed in this letter;
- (2) provide, by August 26, 2019, an accounting containing: (a) the number of infringing contracture boots that TruLife has sold in the last six (6) years and TruLife's gross revenue from those sales, and (b) the number of infringing contracture boots that TruLife has available for sale;
- (3) provide, by August 26, 2019, the name and address of each party from which TruLife has purchased infringing contracture boots;

¹ The shipping label also references: 66906 BOOT TRU-CLEAR CONTRACTURE.

- (4) provide, by August 26, 2019, a sample of any contracture boot that TruLife has sold in the last six (6) years that: (a) was not purchased from BMI, and (b) TruLife contends is not an infringing contracture boot;
- (5) refrain from infringing the '780 Patent under 35 U.S.C. § 271 in the future;
- (6) refrain from infringing the '519 patent under 35 U.S.C. § 271 in the future; and
- (7) provide written confirmation by August 26, 2019 that you have completed requests (1)-(4) listed above and will comply with requests (5) and (6) listed above.

I look forward to hearing from you. This letter is sent without prejudice to BMI's rights, all of which are expressly reserved.

Very truly yours,

LATHROP GAGE LLP

By:

A. Justin Poplin

Enclosures

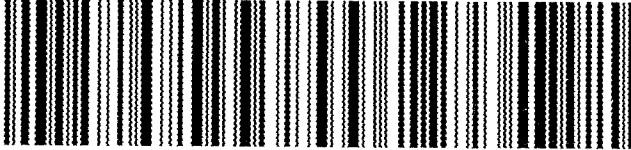
EXHIBIT F

EUS POSTAGE
07/29/2019
From 66210Pitney Bowes 026W0004897439
ComPlsPrice
Flat Rate Envelope 1765742068**PRIORITY MAIL EXPRESS 1-DAY™**Justin Poplin
Lathrop Gage LLP
Bldg 82, Ste 1000
10851 Mastin St
Overland Park KS 66210-1687

Scheduled Delivery Date: 07/30/2019

0007

WAIVER OF SIGNATURE

C001NOEL MURPHY, PRESIDENT
TRULIFE, INC.
2010 E HIGH ST
JACKSON MI 49203-3416**USPS TRACKING #**

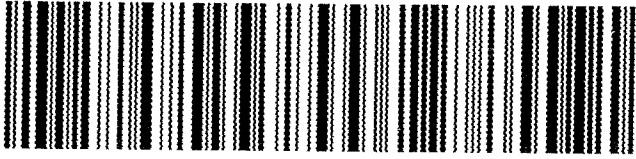
9470 1098 9864 2341 6180 77

EUS POSTAGE
07/29/2019
From 66210Pitney Bowes 026W0004897318
ComPlsPrice
Flat Rate Envelope 1765742068**PRIORITY MAIL EXPRESS 2-DAY™**Justin Poplin
Lathrop Gage LLP
Bldg 82, Ste 1000
10851 Mastin St
Overland Park KS 66210-1687

Scheduled Delivery Date: 07/31/2019

0007

WAIVER OF SIGNATURE

C001SHAWN BOSS, REGISTERED AGENT
TRULIFE, INC.
2010 E HIGH ST
JACKSON MI 49203-3416**USPS TRACKING #**

9470 1098 9864 2341 6393 79

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Tracking Number: 9470109898642341618077

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Scheduled Delivery by

TUESDAY

30 JULY
2019 (i) by
3:00pm (i)

 **Delivered**

July 30, 2019 at 12:49 pm
Delivered, Left with Individual
JACKSON, MI 49203

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July 30, 2019, 12:49 pm

Delivered, Left with Individual
JACKSON, MI 49203

Your item was delivered to an individual at the address at 12:49 pm on July 30, 2019 in JACKSON, MI 49203.

July 30, 2019, 10:25 am

Arrived at Post Office
JACKSON, MI 49202

July 30, 2019, 7:45 am

Arrived at USPS Destination Facility
DETROIT, MI 48242

July 29, 2019, 8:03 pm

Arrived at USPS Regional Origin Facility
KANSAS CITY MO DISTRIBUTION CENTER

July 29, 2019, 5:00 pm

USPS in possession of item
OVERLAND PARK, KS 66223

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